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**STATE OF WISCONSIN**  
**Division of Hearings and Appeals**

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In the Matter of

[REDACTED]  
[REDACTED]  
[REDACTED]

**DECISION**  
Case #: HMO - 174201

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**PRELIMINARY RECITALS**

Pursuant to a petition filed on May 6, 2016, under Wis. Stat. § 49.45(5)(a), and Wis. Admin. Code § HA 3.03, to review a decision by the Division of Health Care Access and Accountability regarding Medical Assistance, a hearing was held on June 28, 2016, by telephone. A hearing scheduled for June 2, 2016, was rescheduled at petitioner's request.

The issue for determination is whether the respondent correctly denied petitioner's request for a TENS unit.

There appeared at that time the following persons:

**PARTIES IN INTEREST:**

Petitioner:

[REDACTED]  
[REDACTED]  
[REDACTED]

;

Respondent:

Department of Health Services  
1 West Wilson Street, Room 651  
Madison, WI 53703

By: [REDACTED]  
Division of Health Care Access and Accountability  
PO Box 309  
Madison, WI 53701-0309

**ADMINISTRATIVE LAW JUDGE:**

Peter McCombs  
Division of Hearings and Appeals

**FINDINGS OF FACT**

1. Petitioner (CARES # ) is a resident of Milwaukee County.

2. On April 1, 2016, the petitioner, with Home Care Medical, requested a transcutaneous electrical nerve stimulation devise ("TENS") unit. The Office of Inspector General denied the request on April 18, 2016, after determining that petitioner's provider had failed to establish that the TENS unit was medically necessary. See, Exhibit R-1.
3. The petitioner is a 52-year-old woman diagnosed with chronic low back pain due to bilateral joint dysfunction. She has previously utilized a TENS unit to address her chronic pain, which provided pain relief, but her TENS unit has is now "worn out." See, Exhibit R-1.
4. Petitioner's medical records do not establish that petitioner's TENS unit treatment is part of an approved clinical study.

### **DISCUSSION**

The petitioner requests a TENS unit to replace her current unit, to address her ongoing chronic lower back pain. She is a 52-year-old woman who has been able to achieve a significant reduction in her lower back pain historically with the use of the TENS unit. TENS units are a type of durable medical equipment that must be authorized by the Office of Inspector General before the medical assistance program will pay for it. See Wis. Admin. Code § DHS 107.24. When determining whether a service is necessary, the Division must review, among other things, the medical necessity of the service, the appropriateness of the service, the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Adm. Code, § DHS 107.02(3)(e)1.,2.,3.,6. and 7. "Medically necessary" means a medical assistance service under ch. DHS 107 that is:

- (a) Required to prevent, identify or treat a recipient's illness, injury or disability; and
- (b) Meets the following standards:
  1. Is consistent with the recipient's symptoms or with prevention, diagnosis or treatment of the recipient's illness, injury or disability;
  2. Is provided consistent with standards of acceptable quality of care applicable to the type of service, the type of provider, and the setting in which the service is provided;
  3. Is appropriate with regard to generally accepted standards of medical practice;
  4. Is not medically contraindicated with regard to the recipient's diagnoses, the recipient's symptoms or other medically necessary services being provided to the recipient;
  5. Is of proven medical value or usefulness and, consistent with s. HFS 107.035, is not experimental in nature;
  6. Is not duplicative with respect to other services being provided to the recipient;
  7. Is not solely for the convenience of the recipient, the recipient's family, or a provider;
  8. With respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient; and
  9. Is the most appropriate supply or level of service that can safely and effectively be provided to the recipient.

Wis. Admin. Code, § DHS 101.03(96m).

The respondent's authorization criteria for TENS units to treat chronic low back pain (CLBP) require:

TENS therapy for CLBP is only covered when all of the following criteria are met:

- a. The beneficiary has one of the following diagnoses listed in the diagnosis section below,

**AND**

- b. The beneficiary is enrolled in an approved clinical study that meets all of the requirements set out in NCD § 160.27 (CMS Internet Only Manual 100-3, Chapter 1). ...

The respondent determined that the petitioner's request demonstrated that petitioner does have a qualifying diagnosis, but it failed to establish that she was enrolled in an approved clinical study. The respondent therefore denied the request.

At hearing, petitioner was unable to refute the contention that she was not enrolled in an approved clinical study. She testified credibly that without the TENS unit she suffers from swelling, and will have to take narcotics to deal with her chronic pain. She reported very poor health without an operational TENS unit.

I have reviewed the testimony and submitted documentation, and I find that the petitioner has not met her burden of proving by the preponderance of the credible evidence that the requested TENS unit is medically necessary. Specifically, she simply has not satisfied the necessary requirements because she is not presently enrolled in an approved clinical study. She must provide actual medical documentation establishing that she is in an approved clinical study, in addition to establishing her CLBP diagnosis, in order to demonstrate the necessity of the requested TENS device. I suggest she find and enroll in such a study, and thereafter submit a new request with this information. If it is denied, she can file a new appeal.

**CONCLUSIONS OF LAW**

The petitioner has established that she has a qualifying diagnosis, but she failed to establish that she was enrolled in an approved clinical study. The respondent therefore correctly denied the request for a TENS unit.

**THEREFORE, it is**

**ORDERED**

The petitioner's appeal is dismissed.

**REQUEST FOR A REHEARING**

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

## APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, **and** on those identified in this decision as “PARTIES IN INTEREST” **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,  
Wisconsin, this 25th day of August, 2016

\s \_\_\_\_\_  
Peter McCombs  
Administrative Law Judge  
Division of Hearings and Appeals



**State of Wisconsin\DIVISION OF HEARINGS AND APPEALS**

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The preceding decision was sent to the following parties on August 25, 2016.

Division of Health Care Access and Accountability